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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/083,456	02/26/2002	Sean D. Monahan	16.06	6485

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MIRUS CORPORATION
505 SOUTH ROSA RD
MADISON, WI 53719

EXAMINER

KETTER, JAMES S

ART UNIT	PAPER NUMBER
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1636

DATE MAILED: 07/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/083,456	Applicant(s) MONAHAN ET AL.	
	Examiner James S. Ketter	Art Unit 1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 April 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-35 is/are pending in the application.
- 4a) Of the above claim(s) 1-18 and 27-35 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 19-26 is/are rejected.
- 7) ☒ Claim(s) 24-26 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>5/11/06</u> . | 6) <input type="checkbox"/> Other: _____ |

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Applicant's election of Group II, claims 19-26, in the reply filed on 21 April 2006 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 1-18 and 27-35 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 21 April 2006.

The disclosure is objected to because of the following informalities: At pages 49-51, there are irregularities in the drawn chemical structures. At page 49, a copy of the graphic of said structures is overwritten onto the second portion of text. If this is due to an IFW scanning error by the USPTO, Applicants should point this out. However, even if such were the case, a replacement page to rectify the image file would be welcome. At page 50, there is overlap of certain portions of the labels and structures such that graphic is potentially confusing. At page 51, the amine and anhydride structures overlap the immediately preceding line of text.

Appropriate correction is required.

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35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 19-25 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

The instant claims encompass naturally-occurring viruses and bacteriophages. The membrane-active compound would correspond to the portion of a polypeptide coat protein that determines infectivity or specificity of infection by binding to the cell membrane or proteins therein. Clearly, many viruses begin the infection of a cell by such a first step, whether at the cell membrane or within a lumen or vesicle bounded by a membrane. The remainder of the polypeptide, attached through a peptide bond, represents the polymer. A peptide bond is a labile linkage, and as such, the membrane-active compound and the polymer portions of the complex necessarily contain labile bonds/linkages.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 19-25 are rejected under 35 U.S.C. 102(b) as being anticipated by Valerio et al. (WO 97/05266, newly cited as reference N on the attached PTO-892).

As set forth above, the instant claims encompass naturally-occurring viruses and bacteriophages, as well as a virus to which a targeting moiety has been attached. The membrane-active compound would correspond to the portion of a polypeptide coat protein that determines

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infectivity or specificity of infection by binding to the cell membrane or proteins therein.

Clearly, many viruses begin the infection of a cell by such a first step, whether at the cell membrane or within a lumen or vesicle bounded by a membrane. The remainder of the polypeptide, attached through a peptide bond, represents the polymer. A peptide bond is a labile linkage, and as such, the membrane-active compound and the polymer portions of the complex necessarily contain labile bonds/linkages.

Valerio et al. teaches, e.g., at the Abstract, viral gene delivery vehicles comprising a gene of interest to be delivered to the cell, a viral capsid carrying a member of a specific binding pair which binds to a second binding pair member which binds to the outer surface of the target cell. Proteins or antibodies are taught as the targeting conjugates.

Claims 24-26 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim should refer to other claims in the alternative only. See MPEP § 608.01(n). Each of the instant claims depends on both claims 20 and 21.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 19-26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Claims 19, 20, 22 and 23, and therefore dependent claims 21 and 24-26, recite “membrane-active compound”. However, it is not clear from either the specification or the prior art what defines a membrane-active compound. The metes and bounds of the instant claims are thus unclear.

Claims 24-26 depend from claims 20 or 21, which are drawn to a complex. However, claims 24-26 are drawn to a process. This appears to be in error; however, as drafted, the claims are of unclear statutory class and thus fail to particularly point out and distinctly claim the subject matter which Applicants regard as their invention.


Claim 24 recites “pH-labile”, “very pH-labile” and “extremely pH-labile”. However, “very” and “extremely” are relative terms, and are not clearly defined in either the specification or the prior art, in the present context. As such, the meaning of the claim is unclear.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James S. Ketter whose telephone number is 571-272-0770. The examiner can normally be reached on Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner’s supervisor, Remy Yucel can be reached on 571-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JSK
7 July 2006



JAMES KETTER
PRIMARY EXAMINER